

*REMARKS/ARGUMENTS**Status of the Claims*

Claims 23-50 are pending. Claims 1-22 and 51-65 have been cancelled without prejudice. Applicants reserve the right to pursue the subject matter of the cancelled claims in a continuing application.

*Discussion of Section 103 Rejections*

Claims 1-65 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over 70-5191-00-8 (Pfizer Labs, Division of Pfizer Inc., NY, NY 10017 (October 2003)) referred to "Zithromax" in view of U.S. Patent No. 6,365,574 (Singer). Applicants traverse.

Pending claims 23-50 are directed to a method of producing a composition comprising lyophilized azythromycin, which comprises an ethanolate of azithromycin. There is no teaching or suggestion in either the Zithromax or Singer of a method for producing a stable, sterile pharmaceutical product/formulation comprising lyophilized azithromycin containing ethanol in an amount from about 0.005% to about 0.5% by weight of the pharmaceutical formulation as recited in pending claims 23-50.

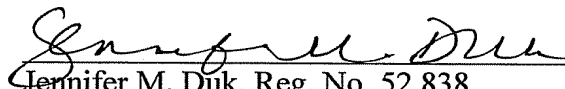
Neither Zithromax nor Singer describes the conditions under which a lyophilized formulation of azithromycin is produced including, for example, the freeze temperature, the primary drying temperature, the secondary drying temperature and the times for each of these stages. The conditions for successful lyophilization vary widely for each active ingredient and even for different forms of an active. Therefore, in view of the limited teachings of the cited references, it would not have been obvious in view of the cited references to produce a lyophilized azithromycin containing ethanol in an amount from about 0.005% to about 0.5% by weight of the pharmaceutical formulation under the specific conditions recited in pending method claims 23-50.

In sum, the combination of Zithromax and Singer does not result in the invention of pending claims 23-50 and therefore, there is no prima facie case of obviousness. Accordingly, Applicants request that the obviousness rejection be withdrawn.

*Conclusion*

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

  
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